

Application Serial No. 09/817,446  
Attorney Docket No. SAFTY-001BC

a cover sealed over the cavity of the base, the cover comprising at least one sample port disposed over the at least one filtrate receiving vessel to permit filtrate from a sample to flow through the sample port into the filtrate receiving vessel;

at least one membrane module disposed over the at least one sample port of the cover, the at least one membrane module having a receiving cavity for receiving a sample to be filtered, and a filter for filtering the sample, wherein the receiving cavity of the at least one membrane module comprises a plurality of concentric rings of a hard material and an elastomeric material; and

a second membrane module nested in the at least one membrane module disposed over the at least one sample port.

### REMARKS

Claims 1-7 and 67-78 were pending. By way of this response, claims 1, 7, 67-69, 72, and 78 have been amended. In addition, the specification has been amended to correct minor syntactical and word-processing errors.

#### Items 3 and 4 of the Office Action

Claims 68-78 were withdrawn from consideration as being elected to a non-elected invention as the result of a restriction requirement that was made by the Examiner in item 3 of the Office Action. The restriction requirement was made final. However, Applicants vigorously disagree with the Examiner's finding that the Inventions of Groups 1 (claims 1-7), II (claims 68-77), and III (claim 78) are unrelated and Independent inventions, and respectfully requests that both the restriction requirement and the finality of that requirement be reconsidered.

The Examiner explains the restriction requirement by stating that the different inventions "... have different required components that have different

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modes of operation and functions." Further, the Examiner attempts to support this finding by asserting that:

1) The feature of a differential pressure source to cause pressure differential between each of the sample wells and each of the filtrate receiving vessels of Group I is not required by the claims of Group II and III;

2) The feature of a cover that seals over the cavity of the base and comprised of a sample port disposed over the filtrate receiving vessel of Group II is not required by the claims of Group I and III; and

3) The feature of a second membrane module nested in the membrane module disposed over the sample port of Group III is not required by the claims of Group I and II.

All three of the above assertions are incorrect. For instance, claim 71 of Group II recites that the apparatus comprises "a port within the base to facilitate a decrease in pressure within the cavity of the base." A patentability search for an apparatus including such a port would be coextensive with a search for an apparatus including a differential pressure source (since such a source would have to be coupled to a port of some type), and would not increase the burden on the Examiner. Furthermore, with respect to the invention of Group III, while it is true that claim 78 does not positively recite the differential pressure source, this is merely a difference in scope between Group III and the other Groups and is not evidence that the inventions claimed therein "are unrelated and independent."

Similarly, the Examiner is incorrect in stating that "the feature of a cover that sealed over the cavity of the base and comprised of a sample port disposed over the filtrate receiving vessel of Group II is not required by the claims of Group I and III." Lines 13-16 of the first amended version of Claim 1 filed with the response of April 29, 2002 clearly recite that apparatus includes "a lid for sealing each of said sample receiving vessels and said cavity of said housing, the lid having at least one sample port . . ." This differs from claim 68 only in that it uses

the term "lid" rather than "cover", and that it does not explicitly state that the sample port is disposed over the filtrate receiving vessel. However, with respect to the former of these differences, the terms "lid" and "cover" are generally considered to be synonymous. With respect to the latter difference, claim 1 does state that the at least one membrane component " . . . is positioned over the open end of the at least one filtrate-receiving vessel. . . ", and that the edge of the sample port "is structured to retain the at least one membrane component", which would lead one of ordinary skill in the art to infer that the sample port is disposed over the filtrate receiving vessel. In addition, lines 5-7 of the original version of claim 78 filed on April 29, 2002 clearly recite that the apparatus includes "a cover sealed over the cavity of the base, the cover comprises at least one sample port disposed over the filtrate receiving vessel."

The Examiner also errs in asserting that "the feature of a second membrane module disposed over the sample port of Group III is not required by the claims of Group I and II. This feature is clearly suggested, if not explicitly stated, in lines 1-2 of Claim 67, as presented in the response filed April 29, 2002, which describe membrane components that are "configured to nest within one another when stacked." The difference here is a primarily a difference in terminology -- the word "component" being used interchangeably with "module" -- and certainly is not sufficient to make the invention of Group III independent and distinct from the invention of Group I. As for the invention of Group II, claims 72 and 73 describe a pair of nested membrane modules disposed over the rim surrounding the at least one sample port. Structurally, this is the same feature as described in Group III. Only the scope and language are different.

In short, the "originally presented invention" as set forth in claims 1-7 and 67 comprised: a base having a cavity formed therein; at least one filtrate receiving vessel disposed in the cavity of the base; a cover (or lid) sealed over the cavity of the base, the cover comprising at least one sample port disposed over the at least one filtrate receiving vessel; and a pair of nested membrane

modules (or components) disposed over the at least one sample port. The inventions of Groups II and III, as identified by the Examiner, do not deviate significantly from this originally presented invention. They do not have different modes of operation, different functions, or different effects; nor do they involve different patentability considerations. Accordingly, the restriction requirement is improper and should be withdrawn.

Items 8-11 of the Office Action – Rejections under 35 U.S.C. §112

Claims 1-7 and 67 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In addition, Claims 1-7 and 67 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both of the above grounds of rejection appear to be based on some confusion or misunderstanding regarding the recitation of “a lid for sealing each of said filtrate receiving vessels and said cavity of said housing, the lid having at least one sample port bounded by an edge extending from the surface of the lid away from the cavity [wherein] the edge is structured to retain the at least one membrane component” in lines 16-20 of claim 1. Specifically, the Examiner alleges that “such a lid is not disclosed in the specification as originally filed,” and questions how “it is possible for a lid to individually seal each filtrate receiving vessel and also the cavity of the housing.”

The “lid” in claim 1 was actually intended to refer to cover 12 of the test apparatus shown in Figs. 5-9 of the present application, and described in page 13, line 10 through page 18, line 25 of the specification. Sealing lids 24 may actually be considered to be part of the cover. Thus, when the lids 24 are in place, the cover 12 does indeed seal each individual filtrate receiving vessel 15 as well as the cavity 17 of the housing 16. Furthermore, the cover 12 has at

least one sample port 13 bounded by a rim 28 extending from the surface of the cover 12 away from the cavity 17. The rim is structured to retain at least one membrane module 18 or 20.

In order to obviate any possible misunderstanding and to ensure greater consistency of terminology between the specification and claims, the word "lid" has been replaced throughout claim 1 with the word "cover." Similarly, the word "edge" has been replaced with "rim" and the word "component" has been replaced with "module." Since the words "cover", "rim" and "module" are generally synonymous with "lid", "edge" and "component," respectively, and since the use and meaning of these words is supported on pages 13-18 of the specification, this change in the wording of claim 1 is not believed to be new matter or a new issue. Thus, Applicants assert that entry of twice-amended claims 1-7 and 67 is clearly in order.

The amendments to claims 68-78 have been made strictly to correct errors in syntax, or to provide antecedent basis for terminology for which such basis was lacking in the originally presented claims. Again, these amendments do not include new matter or raise new issues. Accordingly, it is submitted that amended claims 68-78 should be entered.

Items 12-13 of the Office Action – Rejection under 35 U.S.C. §102

Claims 1-2, 4-7 and 67 were rejected under 35 U.S.C. §102(b) as being anticipated by Clark et al. (U.S. Patent No. 4, 902,481).

Claim 1 (twice amended) of the present application is directed to an apparatus for non-electrophoretic determination of the presence of at least one analyte in at least one flowable sample. The apparatus comprises a housing (16) having at least one cavity (17). At least one filtrate receiving vessel (15) is received in the cavity (17). At least one membrane module (20) is positioned over the open end of the at least one filtrate receiving vessel. The membrane module includes a sample-receiving well so that a sample placed within a

particular sample receiving well is filtered through the associated membrane component, and a filtrate which emerges from that membrane component will be received within the associated filtrate-receiving vessel. A cover (12) is provided for sealing each of the filtrate receiving vessels (15) and the cavity (17). The cover includes at least one sample port (13) bounded by a rim (28) extending from the surface of the cover (12) away from the cavity (17). The rim (28) is structured to retain the at least one membrane module (20). In addition, the apparatus includes a differential pressure source that causes a pressure differential between each of the sample-receiving wells and each of the filtrate-receiving vessels, the pressure differential being operative to drive each sample through the associated membrane component and the resultant filtrate into the associated filtrate-receiving vessel.

The patent to Clark et al. (U.S. Patent No. 4,902,481) discloses a filtration apparatus comprising a housing (2) having a cavity formed therein; a receiving plate (8) having a number of chambers (9) for receiving filtrate, a plate (13) that houses a membrane (30) and is positioned over the open end of each chamber (9), and a support (10) that covers the receiving plate (8) and the cavity of the housing (2). A filtration plate (12) having a number of sample-receiving wells (11) is positioned above the support (10). A vacuum assembly is coupled to the housing.

The Examiner apparently takes the position that the support (10) shown in Clark et al. ('481) reads on the "lid" or "cover" of claim 1, and that the membrane (30) together with the filtration plate 12, reads on the "at least one membrane component." Applicants respectfully disagree.

Among other things, Claim 1 (twice amended) sets forth the limitation, in lines 14-17, that the cover includes sample ports, and that each port is bounded by a rim that extends away from the cavity and is structured to retain a

membrane module. Essentially the same limitation is set forth in Claim 68 (Amended), lines 6-10, and Claim 78 (Amended), lines 6-9.

The "cover" or support (12) of Clark et al. ('481) does not include any sample ports; nor does it have a rim that retains any membrane modules. Instead, the sample ports (11) and membrane (30) are provided as part of a separate filtration plate (12). Furthermore, the support (12) of Clark et al. does not seal the individual filtrate receiving vessels (9) of the apparatus. Accordingly, independent claims 1 (Twice Amended), 68 (Amended), and 78 (Amended) are not anticipated under 35 U.S.C. 102(b), which requires that an anticipating reference disclose each and every feature of the claimed invention.

Claims 2-7 and 69-77 depend from Claims 1 and 68, respectively, and thus distinguish over Clark et al. for the same reasons as Claim 68. In addition, Claims 2-7 and 69 include numerous other features that are neither shown nor suggested by Clark et al.

For instance, Claim 7 recites that at least one of the membrane modules has portions made of a first hard material and portions made of a second elastomeric material, wherein the elastomeric portions abut against neighboring components of the apparatus to provide substantially air tight sealing therebetween. Claims 74-77 recite, among other things, that the hard and elastomeric portions of the membrane components are formed as a plurality of concentric rings. The "membrane module" or filtration plate 12 of Clark et al. ('481) includes no elastomeric portions abutting against neighboring portions of the apparatus, let alone rings of elastomeric material that alternate concentrically with rings of hard material, as described in Claims 74-77. Accordingly, Claims 7 and 74-77 clearly distinguish over Clark et al. ('481).

Items 14-15 of the Office Action – Rejection under 35 U.S.C. §103

Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. ('481) in view of Oprandy.

The Examiner alleges that the patent to Clark '481 discloses all the claimed features of the invention, except for the positive pressure source, and that it would be obvious to provide such a source in view of the teachings of Oprandy. As argued above, however, there are various other features of the present invention that Clark ('481) does not disclose. For instance, Clark ('481) does not disclose a cover that seals both the cavity of the test apparatus housing and each of the individual filtrate-receiving vessels, wherein the cover includes at least one sample port bounded by an edge structured to retain at least one membrane component. Oprandy does nothing to overcome this particular shortcoming of Clark ('481). Accordingly, Claim 3 is neither anticipated, suggested, nor made obvious by Clark et al. ('481) in view of Oprandy.

Conclusion

In view of the above, Applicants submit that the rejections under 35 U.S.C. § 112, first and second paragraphs, 35 U.S.C. § 102(b), and 35 U.S.C. § 103(a) have been overcome. Furthermore, Applicants submit that the restriction requirement, the "constructive election by original presentation," and the finality of the restriction requirement are improper, and should be withdrawn.

In addition, Applicants submit that the amendments and remarks included herein do not raise new issues, but merely correct obvious errors in the specification and claims, and place the application in clear condition for allowance, or alternatively, in better condition for appeal. Accordingly, Applicants respectfully request that the amendment and remarks be entered, and the application be allowed.



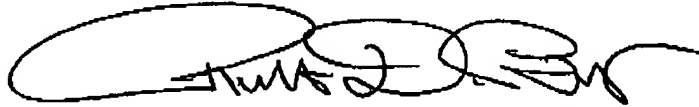
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The above amendments and remarks are believed sufficient to address all of the issues raised in the Office Action. The Examiner is encouraged to contact the undersigned by telephone if there is any further hindrance to allowance of the present application.

Respectfully submitted,

STOUT, UXA, BUYAN & MULLINS, LLP

Date: December 23, 2002



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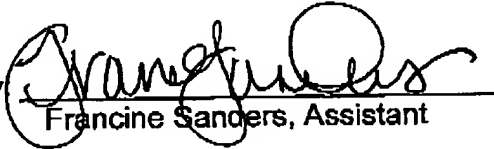
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I hereby certify that this correspondence is transmitted by facsimile to (703) 872-9307 to BOX AF, Commissioner for Patents, Washington, D.C. 20231 on December 23, 2002:

Dated: December 23, 2002

By

  
Francine Sanders, Assistant

**APPENDIX SETTING FORTH MARKED-UP COPY OF SPECIFICATION**

The paragraph beginning at page 3, line 9 has been amended as follows:

In accordance with the invention, there are provided certain apparatus for non-electrophoretic testing of samples, such apparatus generally comprising a) one or more vessel(s) for receiving sample(s), b) one or more membrane modules which are positioned in alignment with the sample vessels(s) such that sample will pass through the membrane(s), and c) one or more filtrate receiving vessel(s) such that sample will pass through the membrane(s), and c) one or more filtrate receiving vessels positioned in alignment with the membrane modules, to receive filtrate which has passed through the membranes. Various numbers of membrane modules may be used, stacked upon one another, to remove particles, interferants or other unwanted matter from the sample and/or to capture certain analyte(s) for subsequent elution from the capture membrane and determination by suitable visual or analytical means. The test apparatus may include positive or negative pressure apparatus to [crate] create differential pressure within the apparatus for driving the [sample(s)] samples through the membranes. Also, these apparatus may have a) specialized pressure equalization ports to ensure efficient and complete processing of all samples, b) selective engagement apparatus for engaging and disengaging the membrane modules and other components to/from one another and to form substantially air tight seals therebetween when assembled, c) specific configurations to allow the membrane modules and other components to nest or register with one another in a manner which facilitates proper orientation and functional positioning of all components, d) specific construction and mounting of membranes to deter tearing or rupture of the membranes during operation, and to maximize the functional surface area of the membrane(s), and (e) structural attributes which hold multiple membranes in close-spaced, stacked relation to each other during operation.

The paragraph beginning on page 5, line 22, has been amended as follows:

Figure 13 [a] is an exploded view of an alternative membrane module useable in the apparatus of Figure 12.

The paragraph beginning on page 6, line 7 has been amended as follows:

Figure 15d [showes] shows the component of [figure] Figure 15c from an angle which allows one to see the underside of that component.

The paragraph beginning on page 12, line 8 has been amended as follows:

Figure 4 shows a [bock] block diagram of a general method whereby the test methods and apparatus of the present invention may be used to predict the occurrence of certain changes (e.g. oxidation, other degradation, spoilage) which a sample is likely to undergo within a given time period. These techniques may be used as predictors of [.] shelf life, propensity for oxidative degradation, presence of contaminants, etc. Specific examples of this general method are set forth in detail herebelow.

Please amend the paragraph beginning on page 12, line 19 as follows:

Thereafter, aliquots of the prepared sample are placed in separate vessels. One sample is subjected to a stress (e.g., heat, light, air, etc.) which is known to promote the particular change which is sought to be predicted. (e.g., oxidation, degradation, etc.)

Please amend the paragraph beginning on page 12, line 27 as follows:

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The results of the analyte determinations are then processed by way of an algorithm or formula, to arrive at the desired prediction as to whether the sample will undergo the particular change (e.g., oxidation, degradation, etc.) [Within] within a particular time period. Examples of specific algorithms which are useable in this regard are shown in the table of Appendix IV.

The paragraph beginning on page 15, line 5 has been amended as follows:

The elastomeric EM portions of the membrane modules 20, 18 are configured and located to abut against the adjacent membrane module(s) 20, 18 and/or against the adjacent sample port rim 28, to effect a substantially air-tight seal therebetween. The sealing contact between the membrane modules 20, 18 and the sample port rims 28 may be facilitated by the interaction of connector members 40, 42 formed thereon. In this regard, the [rim] rims 28 of each sample port 13, and of each secondary membrane module 18, are provided with first connector members such as projections 40. Each primary and secondary membrane module 20, 18 is also provided with corresponding second connector members such as slots 42, into which the first connector members 40 will insert and engage to thereby hold the primary and secondary membrane modules 20, 18 in stacked, sealing contact upon each sample port 13 as shown.

**APPENDIX SETTING FORTH MARKED-UP COPY OF AMENDED CLAIMS**

1. (Twice Amended) An apparatus for non-electrophoretic determination of the presence of at least one analyte in at least one flowable sample, said apparatus comprising:
- a housing having a cavity formed therein;
  - at least one filtrate-receiving vessel positioned within the cavity of the housing, the filtrate-receiving vessel having an open end;
  - at least one membrane [component] module positioned over the open end of the at least one filtrate-receiving vessel;
  - at least one sample-receiving well, each sample-receiving well being positioned in association with one of said membrane components such that sample placed within a particular sample receiving well is filtered through the associated membrane [component] module, and a filtrate which emerges from that membrane [component] module will be received within the associated filtrate-receiving vessel;
  - a [lid] cover for sealing each of said filtrate receiving vessels and said cavity of said housing, the [lid] cover having at least one sample port bounded by [an edge] a rim extending from the surface of the lid away from the cavity, and the [edge] rim is structured to retain the at least one membrane [component] module; and
  - a differential pressure source to cause a pressure differential between each of said sample-receiving wells and each of said filtrate-receiving vessels, said pressure differential being operative to drive each sample through the associated membrane [component] module and the resultant filtrate into the associated filtrate-receiving vessel.

7. (Twice Amended) The apparatus of Claim 1 wherein at least one of said membrane [components] modules [have] has portions formed of a first hard material, and portions formed of a second elastomeric material, the portions formed of said elastomeric material being at locations which abut against

neighboring components of the apparatus to provide substantially air tight sealing therebetween.

67. (Twice Amended) The apparatus according to Claim 1 wherein the at least one membrane module comprises a plurality of membrane modules, and at least [one] two of the membrane [components] modules are configured so as to nest within one another when stacked, thereby ensuring proper alignment of the membrane [components] modules to allow sample to flow through each sample flow channel.

68. (Amended) An apparatus for non-electrophoretic determination of the presence of at least one analyte in at least one flowable sample, said apparatus comprising:

a base having a cavity formed therein;

at least one filtrate receiving vessel disposed in the cavity of the base;

a cover sealed over the cavity of the base, the cover [comprises] comprising at least one sample port disposed over the at least one filtrate receiving vessel to permit filtrate from a sample to flow through the sample port into the filtrate receiving vessel, the at least one sample port surrounded by a rim extending from the cover away from the at least one filtrate receiving vessel; and

at least one membrane module disposed over the rim surrounding the at least one sample port of the cover, the at least one membrane module having a receiving cavity for receiving a sample to be filtered, and a filter for filtering the sample.

69. (Amended) The apparatus of Claim 68 wherein:

the at least one filtrate receiving vessel comprises a plurality of filtrate receiving vessels;

the at least one sample port comprises a plurality of sample ports, each of the sample ports being disposed over a different one of the filtrate receiving vessels;

a plurality of membrane modules, each of the membrane modules being disposed over the rim surrounding a different one of the sample ports; and

wherein the cover further comprises [comprising] a lid disposed on [each of] the receiving [cavities] cavity of [the at least one] each of the membrane [module] modules.

72. (Amended) The apparatus of claim 68 further comprising at least one second membrane module nested in the at least one membrane module disposed over the membrane module disposed over the rim surrounding the at least one sample port.

78. (Amended) An apparatus for non-electrophoretic determination of the presence of at least one analyte in at least one flowable sample, said apparatus comprising:

a base having a cavity formed therein;

at least one filtrate receiving vessel disposed in the cavity of the base;

a cover sealed over the cavity of the base, the cover [comprises] comprising at least one sample port disposed over the at least one filtrate receiving vessel to permit filtrate from a sample to flow through the sample port into the filtrate receiving vessel;

at least one membrane module disposed over the at least one sample port of the cover, the at least one membrane module having a receiving cavity for receiving a sample to be filtered, and a filter for filtering the sample, wherein the receiving cavity of the at least one membrane module comprises a plurality of concentric rings of a hard material and an elastomeric material; and

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a second membrane module nested in the at least one membrane module  
disposed over the at least one sample port.